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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/403,844	04/18/1995	OYSTEIN FODSTAD	7885.33USWO	4228

23552 7590 11/12/2003

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/403,844

Applicant(s)

FODSTAD ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 41,42,80-86,90,91,94,95,97,98,100 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25,28,29,33-40,43,46,47,59,62,64,87-89,96,101,106,108-111,116 and 117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 22-25,28,29,33-43,46,47,59,62,64,80-91,94-98,100,101,104,106,108-111,116 and 117.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 22-25,28,29,33-43,46,47,59,62,64,80-91,94-98,100,101,104,106,108-111,116 and 117.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/03 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 7/28/03 in Paper No. 50 is acknowledged and has been entered. Claims 22 and 87 have been amended. Applicant's amendment and response filed 5/28/03 in Paper No. 56 is also acknowledged and has been entered. Claims 46 and 117 have been amended. Claims 41-42, 80-86, 90-91, 94, 95, 97, 98, 100, and 104 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 22-25, 28, 29, 33-43, 46-47, 59, 62, 64, 80-91, 94-98, 100-101, 104, 106, 108-111, and 116-117 are pending. Claims 22-25, 28, 29, 33-40, 43, 46-47, 59, 62, 64, 87-89, 96, 101, 106, 108-111, 116, and 117 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112/103

3. In light of Applicant's amendment, the rejection of claims 46-47, 106, and 117 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

4. In light of Applicant's amendment, the rejection of claims 22-25, 28-29, 33, 36-38, 59, 62, 64, 101, and 108-111 under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) in view of Connelly et al. (US 5,422,277) and in further view of Abram et al. (US 4,497,900), is hereby, withdrawn.

5. In light of Applicant's amendment, the rejections of claims 34-35, 39-40, 43, 46, 47, 87-89, 96, 106, 116, and 117 under 35 U.S.C. 103(a) as being unpatentable over Widder et al. in view of Connelly et al. (US 5,422,277), in further view of Abram et al. (US 4,497,900), as applied to claims 22-25, 28-29, 33, 36-38, 59, 62, 64, 101, and 108-111 above, and further in view of Forrest et al. (U.S. Patent 4,659,678) and Kemmer et al. (Journal of Immunological Methods, 1992) or Holmes et al. (WO 91/09938), are hereby, withdrawn.

6. In light of Applicant's amendment, the rejections of claims 22-25, 28-28, 33-40, 43, 59, 62, 64, 87-89, 96, 101, 108-111, 116, and 117 under 35 U.S.C. 112, first paragraph, as containing new subject matter, is hereby, withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 22-25, 28, 29, 33-40, 43, 46-47, 59, 62, 64, 87-89, 96, 101, 106, 108-111, 116, and 117 are rejected under the judicially created doctrine of double patenting over claims 1-21 of U. S. Patent No. 6,184,043 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of detecting and quantitating specific living target cells in a cell suspension of mixed cell population at a sensitivity of one target cell per 100 or more total cells, comprising coating paramagnetic particles with an antibody or antibodies directed against a membrane structure expressed on the target cells then incubating the paramagnetic particles with the cell suspension under gentle rotation for 5-10 minutes to 2 hours and at 0-25 C. The paramagnetic particles and the cell suspension may be pre-incubated with a mild detergent. After incubation, the mixture can be subjected to magnetic field to separate and isolate the paramagnetic particle-target cell complexes for subsequent examination or analysis of the target cells.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

8. Claims 22-25, 28, 29, 33-40, 43, 46-47, 59, 62, 64, 87-89, 96, 101, 106, 108-111, 116, and 117 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of Fodstad et al. (U.S. Patent No. 6,184,043) in view of Abrams et al. (US Patent 4,497,900).

Fodstad et al. differ from the instant invention in failing to teach that the antibody coated on the paramagnetic particles is directed against a second antibody or antibody fragment that is directed against a cell membrane structure.

Abram et al. disclose an immunoassay for determining the presence of antigen wherein antigen-antibody complexes comprising antigen and antibodies (second antibody) are further incubated (treated) with a primary antibody (first antibody=antiglobulin). Specifically, the primary antibody is directed against the secondary antibody that is bound to the antigen.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use antibodies directed to other antibodies such as taught by Abram to immobilize other antibodies on the surface of the magnetic particles such as in the method of Fodstad et al., because Abram specifically taught that a primary antibody directed against a secondary antibody can be used for binding two elements to form

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complexes, such as a label to an antigen (label -1° antibody- 2° antibody - analyte complexes) or a paramagnetic bead to a cell surface antigen (paramagnetic bead - 1° antibody - 2° antibody - cell surface antigen complexes) and Fodstad specifically has shown that immobilizing specific antibodies on a surface of a solid support, such as magnetic particles is conventional and well within ordinary skill.

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
November 10, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641